Nos. 09-993, 09-1039, and 09-1501

In The
Supreme Court of the United States

Pliva, Inc., et al., *Petitioners*,
v.
Gladys Mensing, *Respondent*.

Actavis Elizabeth LLC, *Petitioner*,
v.
Gladys Mensing, *Respondent*.

Actavis, Inc., *Petitioner*,
v.
Julie Demahy, *Respondent*.

On Writs of Certiorari to the United States Courts of Appeals for the Fifth and Eighth Circuits

BRIEF OF PUBLIC CITIZEN AND AARP AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae Public Citizen and AARP are national non-profit organizations that represent the interests of consumers, including many who regularly use generic prescription drugs. Public Citizen is a membership organization devoted to research, advocacy, and education on a wide range of public-health and consumer-safety issues, including safe, effective, and affordable health care. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and petitioned the Food and Drug Administration (FDA) to act to reduce safety risks. Public Citizen has a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety laws, and its lawyers have represented parties in many significant federal preemption cases, including *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008) (Mem.), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

AARP, an organization for persons 50 years old and over, works to foster the health and economic security of people as they age. To that end, AARP supports efforts at state and national levels to ensure access to safe and effective health care services and products. AARP is concerned about the safety of prescription drugs because older people disproportionately use them. AARP supports

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[1]No counsel for a party authored this brief in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amici curiae* made any monetary contribution to this brief's preparation or submission. The parties' letters of consent to the filing of amicus briefs have been filed with the Clerk.

laws and public policies that protect its members' rights and preserve the availability of legal redress when its members are harmed in the marketplace.

Amici are filing this brief because this case has the potential to broadly impact the safety of prescription drugs. As this Court noted in *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009), "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." They also "serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id.* Generic drugs account for approximately 70 percent of prescriptions filled in the United States. Barring failure-to-warn claims against generic drug manufacturers would decrease the companies' incentive to disclose safety risks promptly, reduce injured consumers' motivation to come forward with information, and deny consumers redress for the injuries they suffer when the drugs they take lack appropriate warnings.

Amici recognize that generic drugs are important in providing affordable drugs to consumers, including the elderly. Indeed, because of the benefits to consumers of having access to generic drugs, representatives of both Public Citizen and AARP testified in support of abbreviated procedures for approval of generic drugs during hearings on the Hatch-Waxman Act when it was being considered by Congress. As AARP testified: "We think that this little bill has the potential for being the biggest consumer interest piece of legislation in this decade." *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 98th Cong.

59 (July 25, 1983). *Amici* are concerned, however, that, through preemption, a statute intended to provide consumers with increased access to *safe* generic drugs will be used to deny consumers necessary protections against *unsafe* ones.

SUMMARY OF ARGUMENT

State-law failure-to-warn claims further the purposes of the Hatch-Waxman Act. In enacting Hatch-Waxman, Congress sought to make generic drugs available to American consumers, but not at the expense of drug safety. The goal was safe, affordable drugs. State-law claims against generic drug manufacturers create incentives for those companies to ensure that their drugs are safe and contain appropriate warnings, and they provide relief to consumers who are injured by generic drug companies' failure to meet their duties of care. In contrast, holding state-law claims against generic drug manufacturers preempted would effectively punish consumers for choosing generic drugs over their name-brand alternatives. And it would send the message that generic drugs are less trustworthy than name-brand drugs—contrary to Congress's goal of reducing drug prices through competition by generic drugs.

That generic drugs do not enter the market until after the patent on the name-brand drug has expired, and therefore not until years after the name-brand drug has been on the market, does not eliminate the need for generic drug manufacturers to be alert to evidence of undisclosed risks and the need for additional warnings. Whether or not drugs are safe and what sorts of warnings are necessary are often not known until drugs have been

on the market for years. Particularly because generic drugs have a large share of the market, it is important that generic drug manufacturers have incentives to promptly and appropriately disclose safety risks.

The extent to which generic drug manufacturers have authority to alter their labels is disputed by the parties here. But it is uncontested that, at the least, they are free to propose new warnings to the Food and Drug Administration (FDA) and to ask the FDA to send "Dear Doctor" letters alerting health-care professionals to newly discovered risks. Because generic drug manufacturers can take measures to ensure that their products have adequate warnings—measures not only permitted but encouraged by the federal regulatory scheme—state-law failure-to-warn claims are not preempted.

ARGUMENT

I. The Hatch-Waxman Act Does Not Sacrifice Safety to Competition.

State-law claims against generic drug companies for failure to fulfill their duty to warn consumers of their products' risks are consistent with the goals of the Hatch-Waxman Act. *See Drug Price Competition and Patent Term Restoration Act*, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Congress passed Hatch-Waxman in 1984 to make low-cost generic drugs more available to the public. *See* H.R. Rep. No. 98-857, pt. 1, at 14 (1984). It estimated that approximately 150 off-patent drugs first approved after 1962 had no generic equivalents and that making generic versions more easily available "would save American consumers $920 million over the [following] 12 years." *Id.* at 17.

Congress sought to achieve the goal of making low-cost drugs available to the public by reducing generic drug companies' barriers to enter the market. To this end, and out of recognition that generic drug companies need not duplicate previously conducted tests to demonstrate that their drugs are safe and effective enough to be approved, the Hatch-Waxman Act releases generic drug manufacturers from the obligation to submit the clinical study results needed to support a new drug application (NDA). Instead, a generic drug manufacturer may submit an abbreviated new drug application (ANDA) containing information showing that the generic drug's conditions of use, active ingredients, route of administration, dosage form, labeling, and strength are the same as those of the corresponding name-brand drug, and that the generic is bioequivalent to the name-brand drug. Pub. L. No. 98-417, § 101, *codified at* 21 U.S.C. § 355(j)(2)(A)(i)-(v).

Although, Hatch-Waxman sought to quickly "make available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14, it did not pursue that aim at all costs. In particular, Congress did not abandon the requirement that drugs be safe. "There is no indication that when Congress passed the Hatch-Waxman Amendments it intended the goal of delivering low cost generic drugs to supplant the FDCA's overall goal of providing consumers with safe and effective drugs." *Gaeta v. Perrigo Pharms. Co.*, __ F.3d __, 2011 WL 198420, at *11 (9th Cir. Jan. 24, 2011). Rather, the policy objective was to "get[] *safe and effective* generic substitutes on the market as quickly as possible." H.R. Rep. No. 98-857, pt. 2, at 9 (emphasis added). Indeed, the law's provisions demonstrate a continued focus on maintaining drug safety and

effectiveness. *See, e.g.*, Pub. L. No. 98-417, § 101, *codified at* 21 U.S.C. § 355(j)(2)(C)(ii) (providing that the Secretary can deny a petition to file an ANDA for a generic drug with a different active ingredient than an approved drug if the drug "may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted" in the ANDA). In short, although the Hatch-Waxman Act's goal was to get low-cost generic drugs to consumers, it did not exchange safety for reduced prices. The Hatch-Waxman Act was intended to be a win-win situation in which generic drugs would be approved more quickly with no decrease in safety or effectiveness.

In crafting a law to increase drug-price competition, Congress focused on market entry, not on post-entry regulation. The Hatch-Waxman Act does not detail generic drug manufacturers' duties after the drug is approved or absolve them of responsibility for the safety of the drugs they manufacture. Indeed, at hearings on the legislation, representatives of the generic drug industry recognized their continuing responsibility for their products after approval. For example, Kenneth N. Larsen, the chairman of the Generic Pharmaceutical Industry Association, stated that generic drug companies were "sensitive to the importance of looking at adverse reactions." *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 98th Cong. 45 (July 25, 1983). "The generic manufacturers of today will respond to those needs," he continued. "If it demands a higher level of knowledge on our part we are prepared to meet and respond to the need." *Id.* Larsen repeated the assurance of drug company responsibility in response to a

question from Representative Waxman about whether the NDA holders were better able to correct problems than generic companies. After acknowledging that the companies that performed the research would have more intimate knowledge of the drug, Larsen assured Mr. Waxman:

> I can state for my company as well as I think I can state for the other generic companies that produce these products, that we will do and provide whatever is required to be performed to meet the regulatory requirement to provide for the safety and well-being of those that are using the drug, this is our role and responsibility. This is an obligation to be in this business.

Id. at 47-48.

Similarly, Bill Haddad, executive officer and president of the Generic Pharmaceutical Industry Association, called concerns about whether generic drug companies would adequately report adverse events a "red herring." *Id.* at 50. "There seems to be a misconception about [] generic drug companies," he noted. "We also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reactions." *Id.* at 50-51. And in response to a question about whether generic drug companies were responsible for reporting adverse event reactions to the FDA, Milton A. Bass, General Counsel to the National Association of Pharmaceutical Manufacturers, which represented

generic drug companies, responded: "Not only yes, Mr. Chairman, but they should be." *Id.* at 47.

In discussing the importance of the Hatch-Waxman Act during the legislative process, members of Congress emphasized their intent to benefit American consumers, particularly older Americans. "Most importantly," Representative Skelton explained in discussing the bill on the House floor, "making generic drugs more available offers some relief to the millions of older Americans whose budgets are strained because medicare does not cover the cost of outpatient drugs. . . . Giving seniors the option of purchasing lower-priced generic drugs is imperative." 130 Cong. Rec. 24437 (Sept. 6, 1984). "Everyone in this country will benefit by enactment of this legislation," Representative Minish agreed, "but I feel it is particularly important that our senior citizens who fill more prescriptions than other segments of our population, can save money on their medical bills." *Id.* at 24456. "This is important legislation," Representative Fish noted. "[I]t is important to the consumer, especially the elderly." *Id.* at 24428.

This Court recently noted that, in enacting the FDCA and its amendments, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers" and "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Wyeth*, 129 S. Ct. at 1199-2000. Congress gave no indication that, in seeking to benefit American consumers through lower drug prices, it intended to decrease generic drug companies' incentives to ensure that their drugs are safe, effective, and contain

adequate warnings, or to deny consumers the ability to seek compensation for injuries caused by drugs with inadequate warnings. Under petitioners' position, however, generic drug manufacturers would have no incentive to ensure that their drugs contain adequate warnings, because they could not be held accountable if their drugs did not.

Moreover, consumers would have no remedies for injuries incurred as a result of inadequate warnings. Many courts, including the Eighth Circuit below, have held as a matter of state law that consumers injured by inadequately labeled generic drugs have no claims against the name-brand manufacturer, because they were not injured by that manufacturer's drug. *See, e.g.*, JA 418-21; *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616 (E.D. Tex. 2010); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643 (W.D.N.C. 2010); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351 (N.D. Ga. 2008); *but see Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). Yet, according to petitioners, injured consumers should also be denied an opportunity to seek compensation from the company that manufactured the drug that they did take. As the Fifth Circuit noted below, however, it would be "bizarre" to hold that "Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of *any* remedy, while under *Levine*, that same plaintiff would have a state-law claim had she only demanded a name brand drug instead." JA 563.

Because Hatch-Waxman's goal was to get *safe* generic drugs into consumers' hands, state-law failure-to-warn claims against generic drug companies further the Act's

purposes, helping to ensure that the companies take reasonable steps to ensure that their drugs contain proper warnings and, therefore, can be used safely. In contrast, denying injured consumers of generic drugs compensation for their injuries would be contrary to the purposes of the Act. In enacting Hatch-Waxman, Congress recognized the importance of generic drugs and the savings that they bring to the public. If generic drug manufacturers are immune from liability, however, injured consumers would essentially be punished for using generic rather than name-brand drugs. Moreover, already, consumers often incorrectly believe that generic drugs are less safe than their name-brand counterparts. *See, e.g.*, FDA, *Facts and Myths About Generic Drugs*, www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (noting the "myths" that "[p]eople who are switched to a generic drug are risking treatment failure," that "[g]eneric drugs cost less because they are inferior to brand name drugs," and that "[b]rand name drugs are safer than generic drugs"). Sending the message that generic drug companies are not accountable for the safety of their products would only further that belief.

II. Risks Associated With a Particular Drug Often Do Not Become Known Until Long After the Drug Has Been Approved.

Generic drugs do not enter the market until after the name-brand drug has been approved and its patent has expired. But the length of time between the initial approval of the name-brand drug and the approval of the generic drug does not ensure the drug's safety or that its label contains adequate warnings. Because risks often do

not become apparent until long after a drug has been approved by the FDA, it is vital that all drug manufacturers—including generic drug manufacturers—have incentives to respond to safety risks as they become known.

The safety of new drugs "cannot be known with certainty until a drug has been on the market for many years." Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawal for Prescription Medications*, 287 JAMA 2215 (2002). A study in the Journal of the American Medical Association on the frequency and timing of the discovery of adverse drug reactions (ADRs) requiring black-box warnings or drug withdrawal concluded that "only half of newly discovered serious ADRs are detected and documented in the *Physicians' Desk Reference* within 7 years after drug approval." *Id.* at 2218. The study noted that Pemoline, a central nervous system stimulant, received its first *Physicians' Desk Reference* black-box warning 22.9 years after it was approved; Danazol, a drug for infertility, received its first black-box warning 15.5 years after approval; and Disopyramide Phosphate, an antiarrhythmic, added its first black-box warning 19.3 years after approval. *Id.* at 2217. In November 2010, the FDA announced that the popular painkiller Propoxyphene (known by the brand names Darvon and Darvocet), which was first approved in 1957, would be removed from the market because of cardiac risks. *See* FDA, *Propoxyphene-Containing Products*, www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm233800.htm. In 2007, 21.3 million prescriptions had been filled for the generic combination of propoxyphene and

acetaminophen, making it one of the most-prescribed generic drugs in the United States. *See* Sidney M. Wolfe, M.D., *Testimony on Propoxyphene (Darvon) Before FDA's Anesthetic, Analgesic and Rheumatologic Drugs and Drug Safety and Risk Management Advisory Committees* (Jan. 30, 2009), *available at* www.citizen.org/Page.aspx?pid=537.

The long history of a black-box warning recently placed on fluoroquinolone antibiotics such as Cipro demonstrates how warnings can change over time, including after both name-brand and generic drugs are approved. The first floroquinolone drug was approved by the FDA in 1986. Over the following years there were reports of tendon inflammation and rupture associated with fluoroquinolones. Based on these reports, in 1996, *amicus curiae* Public Citizen successfully petitioned the FDA to place a warning regarding the risk of tendinopathy and tendon injury on the package insert of fluoroquinolone drugs. *See* Public Citizen, *Petition to Require a Warning on All Fluoroquinolone Antibiotics* (Aug. 1, 1996), *available at* www.citizen.org/hrg1399. The warning was in plain type alongside a list of other risks. Thereafter, however, fluoroquinolone-induced tendon injures continued to occur at an alarming rate. Thus, in 2008, FDA notified manufacturers of the need to add a black-box warning to their labels. *See* FDA, *Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs* (July 8, 2008), *available at* www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126085.htm. This black-box warning was added more than 20 years after the approval of the

first name-brand fluoroquinolone drug, and years after generic versions came on the market.

Because new knowledge can require new warnings, drug manufacturers must take reasonable steps to ensure that their drugs are adequately labeled. As the Court noted in *Wyeth*, "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." 129 S. Ct. at 1202; *see also, e.g., id.* at 1202 n.11 (citing studies showing that FDA resources are inadequate for it to meet its regulatory responsibilities). And although the Food and Drug Administration Amendments Act of 2007 gave the FDA additional resources for drug safety and new authority to compel manufacturers to make labeling changes, *see* Pub. L. No. 110-85, 121 Stat. 823 (2007), "the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does." 153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (Statement of Sen. Kennedy).

Generic drug companies are often in the best position to discover, assess, and take early action to address risks that come to light after the name-brand drug's period of patent exclusivity has ended because, once generic drugs are available, they often have the majority market share for the drug. Overall, approximately 70 percent of prescriptions are filled with generic drugs. *See, e.g.*, FDA, *Facts and Myths About Generic Drugs*. Generic drug manufacturers are already subject to the same

requirements as name-brand drugs regarding the "reporting and recordkeeping of adverse drug experiences." 21 C.F.R. § 314.98(a). They should not be immune from liability under state law if they fail to take reasonable steps to ensure that consumers are properly warned about risks from their products.

III. Generic Drug Manufacturers Can Act to Warn Consumers About the Dangers of Their Drugs.

Respondents' state-law claims allege that petitioners failed to take reasonable care to adequately warn patients of the risks associated with their products. The parties disagree about the scope of generic manufacturers' authority to alter their labels, but they agree that generic manufacturers can take some actions, such as asking the FDA to require a labeling change or to send out a "Dear Doctor" letter. *See* Pliva Br. 48. Indeed, the FDA has advised that, "[a]fter approval of an ANDA, if an ANDA holder believes that new safety information should be added [to a product's labeling], it should provide adequate supporting information to FDA." 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992). State-law claims seeking to hold a generic drug manufacturer accountable for failing to take action that a reasonable manufacturer would take to warn patients of dangers associated with its product—actions that are allowed, even encouraged, by the federal regulatory scheme—are wholly consistent with the goals of and duties imposed by that scheme.

Petitioners note that even if generic manufacturers asked for a warning or a Dear Doctor letter, the FDA might say no. To be sure, on the merits, petitioners may explain the restrictions and obligations of the federal

regulatory scheme and show their compliance with that scheme in support of their arguments that they took reasonable care to warn patients about the risks of metoclopramide. The law of every state allows such evidence and, in some states, requires that it be given substantial weight. *See, e.g., Restatement (Third) of Torts: Prod. Liab.* § 4; 63B Am. Jur. 2d *Prods. Liab.* § 1922 ("As a general rule, compliance with applicable federal standards is relevant but not conclusive evidence in a products liability case."). In this way, the federal regulatory scheme can play an important role in litigating state-law failure-to-warn claims against drug manufacturers.

But the issue here is preemption. Petitioners argue that the regulatory scheme must be preemptive because litigating the case on the merits may require speculation about how the FDA would have responded to manufacturers' efforts to revise the labeling. *See* Pliva Br. 49. Name-brand manufacturers, however, also must seek FDA approval for labeling changes. Yet, in *Wyeth*, the Court held that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." 129 S. Ct. at 1198; *see also id.* (noting that the manufacturer "offered no such evidence"). By declining to hold failure-to-warn claims preempted, while recognizing that drug manufacturers might submit evidence of whether the FDA would have approved a label change, the Court recognized that state-law claims are not preempted whenever they might involve "speculation about what a federal agency would have done in hypothetical proceedings." Pliva Br. 53.

Petitioners attempt to distinguish *Wyeth* on the ground that name-brand manufacturers can change labeling under the "changes being effected" (CBE) process, which allows manufacturers to add or strengthen a warning without prior approval from the FDA, 21 C.F.R. § 314.70(c)(6)(iii)(A)), and that, therefore, "the brand manufacturer's new warnings could have reached consumers without FDA action." Pliva Br. 53. Even assuming that the FDA does not allow CBE changes for generic drugs, however, petitioners are wrong to portray the CBE process as giving manufacturers the ability to make labeling changes without FDA involvement. The CBE process simply allows the drug manufacturer to make the change while the request for permission to revise the labeling is pending, instead of requiring the drug manufacturer to obtain advance approval. *See* 21 C.F.R. § 314.70(c)(6). Thus, even in cases in which changes are made through the CBE process, the FDA may reject the request for a change, just as it might reject a change suggested by a generic drug manufacturer. *Id.* § 314.70(c)(7). Yet *Wyeth* does not hold that claims are preempted because the FDA *might* reject a change made under the CBE process; it concludes that claims are not preempted absent clear evidence that the FDA would not have approved a labeling change. Accordingly, petitioners' "speculation" objection is inconsistent with *Wyeth*.

Citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), petitioners also argue that state-law claims based on manufacturers' failure to take actions such as alerting the FDA to a newly discovered safety risk would "impose extraordinary burdens on the Agency" by "draw[ing] [it] into nationwide litigation." *Id.* at 55.

Notably, the FDA appears not to share petitioners' concerns. Although the United States stated in its petition-stage brief that "the court of appeals appeared to anticipate that the parties could litigate on remand the question of what action FDA would have taken in response to a hypothetical warning proposal from petitioners," it concluded that state-law failure-to-warn claims are not categorically preempted and recommended denying the petition. Br. of the U.S. as *Amicus Curiae* at 10, 20. And although petitioners imply that FDA employees will be forced to spend large amounts of time testifying, Pliva Br. 56-58, FDA regulations provide that employees may not "give any testimony before any tribunal pertaining to any function" of the FDA, "except as authorized by the Commissioner of Food and Drugs." 21 C.F.R. § 20.1; *see generally United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

Petitioners also contend that allowing claims based on manufacturers' failure to take actions such as asking the FDA for a label change should be preempted because they would cause generic drug companies to "inundate FDA with a deluge of submissions" that it "neither wants nor needs." Pliva Br. 30 (quoting *Buckman*, 531 U.S. at 351). But information about safety risks is information that the FDA *does* want and need. Indeed, the FDA has instructed manufacturers that "if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA." 57 Fed. Reg. at 17961. And petitioners' threat that they and other manufacturers will send "meritless" labeling-change requests to the FDA, Pliva Br. 60, is disingenuous. Generic drug companies are unlikely to ask the FDA to

add unnecessary warnings for fear that the FDA might comply with their requests. Moreover, the argument that allowing claims to proceed would cause drug companies to inundate the FDA with proposed labeling changes was made, and implicitly rejected, in *Wyeth*. *See* Br. for PhRMA and BIO as *Amici Curiae* Supporting Pet. at 36-38, in *Wyeth v. Levine*, No. 06-1249.

In any event, the question in determining preemption is not whether manufacturers' efforts to comply with state-law duties might lead to additional regulatory submissions. Rather, the question is whether the state-law claims and the regulatory scheme conflict. Here, there is no such conflict. If a generic drug manufacturer does not take the steps allowed by the regulatory scheme to provide adequate warnings, it should not be permitted to hide behind that scheme to avoid accountability for its actions.

CONCLUSION

The judgments below should be affirmed.

Respectfully submitted,

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PLIVA, INC. ET AL., *Petitioners*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS ELIZABETH, LLC, *Petitioner*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS, INC., *Petitioner*,

v.

JULIE DEMAHY, *Respondent*.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH AND EIGHTH CIRCUITS

BRIEF OF REP. HENRY A. WAXMAN AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS URGING AFFIRMANCE

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BRIEF OF REP. HENRY A. WAXMAN AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS URGING AFFIRMANCE

INTEREST OF *AMICUS CURIAE*

Amicus curiae Rep. Henry A. Waxman is a Member of Congress with an important interest in this case.[1] Rep. Waxman is ranking Member of the House Committee on Energy and Commerce, which has principal responsibility for legislation and oversight in the areas of public health, consumer protection, and food and drug safety. Rep. Waxman is a committed advocate for consumer protection and was a co-author and leading sponsor of the statute at issue in this case, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Amendments).

Rep. Waxman is proud of the benefits generated by the Hatch-Waxman Amendments for American consumers. In 1984, just 19 percent of the prescription drugs in the United States were generic.[2]

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amicus* or his counsel, make a monetary contribution to the preparation or submission of this brief.

[2] Congressional Budget Office, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 1 (July 1998) (CBO Report).

Today, generic drugs account for 70 percent of the prescriptions filled in this country.[3] Generic drugs have played an important role in holding down national spending on prescription pharmaceuticals and have saved consumers many billions of dollars.[4] Research shows that, on average, the cost of a generic drug is 80 to 85% lower than the brand-name product.[5]

Amicus has an important perspective on the question presented. He is a strong supporter of the generic drug industry. This ongoing commitment does not, however, detract from his belief that in enacting the Hatch-Waxman Amendments, Congress did not intend to categorically preempt state-law failure-to-warn claims.

At bottom, this case presents a question of congressional intent. This Court has explained that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citation and internal quotation marks omitted); *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (same). *Amicus* is uniquely situated to address the question of congressional intent at the center of this case.

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[3] Susan Okie, "Multinational Medicines-Ensuring Drug Quality in an Era of Global Manufacturing," 361 NEW ENG. J. MED. 737, 738 (2009).

[4] CBO Report at 1.

[5] Food and Drug Administration, "Facts and Myths About Generic Drugs," available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

Although *amicus* submits this brief in his individual capacity, his views are informed by his experiences as a Member of Congress.

SUMMARY OF ARGUMENT

The Hatch-Waxman Amendments do not categorically preempt state-law failure-to-warn claims. Such claims are generally consistent with the purposes of the Amendments -- to benefit consumers by bringing safe and effective low-cost generic drugs to market. Nothing in the legislative history of the Amendments manifests any congressional intent to abolish all state-law failure-to-warn remedies for injured consumers. Had Congress intended to take that momentous step, it would have issued a clear statement that state law was preempted. At its core, "[p]re-emption fundamentally is a question of congressional intent." *English v. General Elec. Co.*, 496 U.S. 72, 78 (1990). Congress did not intend to preempt all failure-to-warn claims involving generic drugs.

Nor would it be "physically impossible" for generic drug manufacturers to comply with federal law and their state-law duties. Although a generic drug label must be the same as its brand-name counterpart, there are other bases for imposing failure-to-warn liability on generic manufacturers. For example, generic drug makers have the same responsibility as brand-name manufacturers to inform the FDA of any new information about risks that may require a change in the labeling of their drugs. They can also request that the FDA send a "Dear Health Care Professional" letter or coordinate a campaign of such letters, in order to advise physicians and others of

newly available information. If generic manufacturers fail to take such steps, requiring them to pay damages under state law in a failure-to-warn case creates no inconsistency with federal law.

Categorical preemption of failure-to-warn claims would deprive consumers of generic drugs of a remedy available to consumers of brand-name drugs under *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in which this Court held that state-law failure-to-warn claims against brand-name manufacturers are not preempted. Although there are important differences in the regulatory treatment of brand-name and generic drugs, this Court's reasoning in *Levine* militates against categorical preemption here. In particular, this Court's recognition of the longstanding coexistence of state tort remedies and federal regulation of prescription drugs demonstrates that the two systems are in general complementary.

Moreover, petitioners' position in this case would create the peculiar situation in which a plaintiff whose doctor prescribes a generic drug would be deprived of a remedy for a failure-to-warn claim, while under *Levine*, the same plaintiff would be able to bring a state-law claim if he or she had demanded a brand-name drug instead, or if the doctor had chosen to prescribe a brand-name drug without asking the patient. Congress did not intend that use of generic drugs would come at the price of losing a traditional compensatory tort remedy under state law. Given the fact that generic drugs now account for seven out of ten prescriptions filled in the United States, carving out an exception to *Levine* for generic drugs would dramatically weaken the force and reduce the scope of that decision and, at the same

time, leave millions of consumers without any ability to seek a remedy for their injuries.

ARGUMENT

This Court has made clear that a state tort claim is preempted if it is impossible for a defendant to satisfy both its state-law obligation and federal regulatory requirements. *Levine*, 129 S. Ct. at 1196. In addition, "[u]nder ordinary conflict preemption principles a state law that 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives' of a federal law is pre-empted." *Williamson v. Mazda Motor of America, Inc.*, No. 08-1314, slip op. at 5 (Feb. 23, 2011) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

In this case, holding a generic manufacturer liable on a failure-to-warn theory would not impermissibly frustrate the purposes of the Amendments. Nor is there a conflict between a generic manufacturer's duties under state law and the requirements of the Hatch-Waxman Amendments that would warrant a categorical preemption of failure-to-warn claims against generic drug manufacturers.

I. State-Law Failure-To-Warn Claims Are Consistent With The Purposes Of The Hatch-Waxman Amendments.

The Food, Drug and Cosmetics Act (FDCA) requires that manufacturers obtain premarket regulatory approval for all prescription pharmaceuticals before they are introduced into commerce. 21 U.S.C. § 355(a). Manufacturers of new drugs must submit a new drug application (NDA) to

the FDA. *Id.* at § 355(b). The FDA has codified the NDA regulations at 21 C.F.R. Part 314. An NDA must contain, *inter alia*, scientific data demonstrating the drug's effectiveness and safety for its intended use; a statement of the drug's components; and examples of proposed labeling for the drug. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b). "Before approving an NDA ... [the] FDA undertakes a detailed review of the proposed labeling, allowing only information for which there is a scientific basis to be included in the FDA-approved labeling." 73 Fed.Reg. 49603, 49604 (2008). The FDA will reject the proposed labeling if "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).

In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA, which established the federal regulatory framework governing generics.[6] The House Energy and Commerce Committee Report cited "the policy objective" of the bill as "getting *safe* and *effective* generic substitutes on the market as quickly as possible after the expiration of the patent." H. Rep. No. 98-857, pt. 2, 98th Cong. 2d sess. 9 (1984) (emphasis added). The sponsors of the Amendments also stressed the pro-consumer nature of the bill. Rep. Waxman explained:

> The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate

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[6] *See* Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," 54 FOOD & DRUG L.J. 187 (1999).

> reduction in drug prices when a generic is on the market as a competitor.

130 Cong. Rec. 24430 (Sept. 6, 1984) (statement of Rep. Waxman). Sen. Hatch added:

> This is a good bill. *Without compromising the public safety or welfare in the least* it will significantly lower the price of off-patent drugs, by many times in some cases, through increased generic competition.

Id. at 15847 (June 12, 1984) (statement of Sen. Hatch) (emphasis added).

Under the Amendments, once a brand-name drug has been approved by FDA, any drug company may seek permission to market a generic version through a significantly simplified process, known as the abbreviated new drug application procedure, or ANDA. *See* 57 Fed.Reg. 17950, 17951 (1992). ANDA drugs must be the "same as" a name brand drug that has already been approved by the FDA as to active ingredients, route of administration, dosage form, strength, and conditions of use recommended in the labeling. 21 U.S.C. § 355(j)(2)(A)(iii). Generic drug manufacturers need not repeat the clinical work of their brand counter-parts, but instead must establish only the generic drug's bioequivalence with the name brand drug. *Id.* at § 355(j)(2)(A)(iv). The ANDA must also show that the "labeling proposed for the [generic] drug is the same as the labeling approved for" the brand-name drug. *Id.* at § 355(j)(2)(A)(v).[7]

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[7] The FDA permits certain minor differences in labeling between brand-name drugs and generics that are not at issue here. 21 CF.R. § 314.94(a)(8)(iv).

The ANDA process set forth in the Hatch-Waxman Amendments was premised on the idea that a generic pharmaceutical would be shown to be the *same as* the brand-name drug in every significant way — including the labeling. As the House Energy and Commerce Committee Report explained, "[g]eneric copies of any drugs may be approved if the generic is the same as the original drug or so similar that FDA has determined the differences do not require safety and effectiveness testing." H. Rep. No. 98-857, pt. 1, 98th Cong. 2d sess. 14-15 (1984). "[T]he focus of the bill is to provide the [FDA] with sufficient information to assure that the generic drug is the same as the listed drug that has previously been determined to be safe and effective." *Id.* at 21. "[A]n ANDA must contain adequate information to show that the proposed labeling for the generic drug is the same as that of the listed drug." *Id.* at 22.

The 27 years since the enactment of the Hatch-Waxman Amendments have proven the law to be a resounding and spectacular success. Generic medicines are now considered to be a critical component of quality health care and promoting the public health. They advance competition, which lowers drug prices. Lower drug prices reduce the nation's overall health care bill. Indeed, today, a remarkable 70 percent of prescriptions are filled with generic medicines – saving consumers and the federal and state governments tens of billions of dollars annually.[8] Most importantly, lower drug prices

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[8] Generic Pharmaceutical Association, ANNUAL REPORT: GENERICS. A STEADY COURSE IN A SEA OF CHANGE 2

translate into access to life-saving and life-enhancing drugs for many patients who might not otherwise be able to afford their medications.

The success of the Hatch-Waxman Amendments rests primarily with the law's core principle — the assurance of "sameness" between brand and generic drugs, which provides confidence to consumers that generics will be every bit as safe and effective as brand-name drugs. A key component of this "sameness" principle is that manufacturers of generic drugs will be held to the same high standards as brand-name drugs and that any violation of these standards can be addressed with an identical set of legal tools.

As a practical matter, Congress could not have intended it any other way. Consumers' legal rights would have to be protected in the same way regardless of which kind of drug they take. If not, their ability to seek redress in court would depend upon the type of medication that was prescribed, a choice many consumers are not given by either their health plan or their circumstances in life. Congress did not intend for consumers' rights to be categorically eliminated simply because they purchased a generic rather than a brand-name drug.

As a matter of policy, Congress also did not intend such an outcome. Nothing in the legislative history of the Amendments manifests any congressional intent to leave consumers of generics without any remedy in the event of injury.

(2010) (available at http://www.gphaonline.org/sites/default/files/ AnnualReport2010.pdf).

The fact that there is no express preemption provision in the Hatch-Waxman Amendments mirrors the primacy of this "sameness" principle. Congress recognized that the success of these Amendments would depend upon the extent to which consumers are confident that brand-name and generic drugs are the same and are treated the same. To take away an injured consumer's right to a state-law tort remedy simply because she happened unwittingly to take a generic rather than a brand-name drug would constitute an undoing of the very underpinning — the principle of sameness — on which the Amendments were built. This, in turn, would threaten the overall prospects for success of the legislation.

II. There Is No Conflict Between The Hatch-Waxman Amendments And State Law That Would Warrant a Categorical Preemption of Claims Against Generic Drug Manufacturers.

Petitioners have insisted that state-law tort liability for a generic drug manufacturer in a failure-to-warn case is categorically preempted because the manufacturer cannot comply with its labeling duties under both the Hatch-Waxman Amendments and state law. That argument sweeps too broadly. Although a generic drug label must be the same as its brand-name counterpart, there are other bases for imposing failure-to-warn liability on generic manufacturers.

For example, generic drug makers can and should — and, indeed, do — provide the FDA with any new information they obtain regarding safety hazards

associated with their products, just as brand-name manufacturers do.[9] If a generic manufacturer fails to inform the FDA of such new developments, requiring it to pay damages under state law in a failure-to-warn case creates no inconsistency with federal law and is not preempted.

This is especially true given the basic record-keeping and reporting requirements with which both brand-name and generic manufacturers must comply.

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[9] At hearings on the Hatch-Waxman Amendments, representatives of the generic drug industry stressed that they were willing to keep FDA informed of the risks of their products. *See* New Drug Application: Hearings on H.R. 3605, The Drug Price Competition Act, House Committee on Energy & Commerce, Subcommittee on Health and the Environment, 98th Cong., 1st sess. 45 (July 15, 1983) ("I, too, would like to comment on this adverse reaction issue that was brought up. I can speak as a manufacturer and for two other generic companies in whose representatives are in attendance that are sensitive to the importance of looking at adverse reactions. We are sensitive and responsible. The generic manufacturers of today will respond to those needs. As far as I know we have not been remiss in that responsibility. If it demands a higher level of knowledge on our part we are prepared to meet and respond to the need.") (testimony of Kenneth N. Larsen, chairman of the Generic Pharmaceutical Industry Association); *id.* at 50-51 ("[G]eneric companies . . . also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reaction.") (testimony of Mark Haddad, member of the board of directors of the Generic Pharmaceutical Industry Association).

Both brand-name and generic manufacturers are statutorily required to keep records of clinical experiences and ensure that their products remain safe and effective as labeled. 21 U.S.C. § 355(k). FDA regulations mandate that all manufacturers record and report adverse events. 21 C.F.R. § 314.80(a) and (c) (brand-name manufacturers); *id.* at § 314.98(a) (generic manufacturers). Manufacturers must submit annual reports including, *inter alia*, a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and a "description of actions the applicant has taken or intends to take as a result of this new information." *Id.* at § 314.81(b)(2)(i).

In commentary accompanying the FDA's implementation of the Hatch-Waxman Amendments, the FDA stated:

> If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

57 Fed.Reg. 17950, 17961 cmt. 40 (Apr. 28, 1992).

A generic manufacturer that becomes aware of safety issues can also use a "Dear Health Care Professional" (DHCP) letter to warn physicians and

others of the risks associated with the drug. *See* 21 C.F.R. § 200.5 (setting standards for such letters). A generic manufacturer can take steps to work together with the FDA to ensure that such a letter is distributed to health care professionals. The manufacturer can request that the FDA send out a letter or that the agency otherwise coordinate a DHCP letter campaign.[10]

The responsibility of both the brand-name and generic drug manufacturers to alert the FDA to new safety hazards is a critical one, so that the agency can ensure that labels accurately reflect the most up-to-date information and can also ensure consistency between the treatment of brand-name drugs and their generic equivalents. As this Court noted in *Levine*, "risk information [regarding pharmaceuticals] accumulates over time and that the same data may take on a different meaning in light of subsequent developments." 129 S. Ct. at 1197. The Court further noted that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id.* at 1202.

To be sure, generic drug manufacturers do not conduct or replicate the full clinical trials necessary for the initial approval of a brand-name drug, nor are they expected to do so, because it could well prevent

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[10] DHCP letters are considered a form of "labeling" under the FDCA, 21 U.S.C. § 321(m), and therefore are subject to FDA review and regulation to ensure that they are not false or misleading. *See id.* at § 352(a); 21 C.F.R. § 201.100(d)(1); *id.* at § 314.150(b)(3).

them from bringing a lower-cost generic version to market. *See* H. Rep. No. 98-857, pt. 1, 98th Cong. 2d sess. 16 (1984). But generic manufacturers often receive important risk information once their drug is on the market, and they should be treated the same as brand-name manufacturers with respect to their responsibility to bring relevant data to the FDA's attention.

There is no conflict between federal law and state failure-to-warn liability of generic drug manufacturers that would warrant a categorical preemption of all claims against them. It is clear that a generic and a brand-name label must be the same and that a generic firm cannot unilaterally change its label. To permit individual generic drug labels to differ significantly from their brand-name counterparts—particularly with respect to safety information—would thwart the "sameness" goal reflected in the Hatch-Waxman Amendments. However, it is not only possible for a generic manufacturer in possession of important risk information to take steps to notify FDA that a labeling change may be necessary, but it is, in fact, also encouraged and recommended by FDA. Therefore, generic manufacturers can fulfill both federal and state law in this respect; indeed, it is essential that they do so to fulfill the Hatch-Waxman goals of ensuring drug safety and consumer protection.

III. This Court's Reasoning In *Wyeth v. Levine* Is Applicable To Generic Drugs.

In *Levine*, this Court held that the FDCA did not preempt state-law failure-to-warn claims against

brand-name manufacturers. The Hatch-Waxman Amendments and their legislative history confirm that this Court's reasoning in *Levine* can be applied in certain respects to suits involving generic drug makers as well. *Levine* recognized that drug manufacturers bear a key responsibility for collecting and transmitting information regarding the safe and effective use of their products. In fact, this Court found that multiple reports of adverse drug experiences provided the substantiation necessary to justify a request for a heightened warning. 129 S. Ct. at 1197.

This Court's reasoning in *Levine* is instructive. The Court began with the fundamental assumption, equally salient here, "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 129 S. Ct. at 1194-95. This Court noted the longstanding coexistence of state tort remedies and federal regulation of prescription drugs:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, ... Congress has not enacted such a provision for prescription drugs.... Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the

> exclusive means of ensuring drug safety and effectiveness.

Id.

In particular, the Court explained that "failure-to-warn actions ... lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 1202. Congress "determined that widely available state rights of action provided appropriate relief for injured [drug] consumers" and that "state-law remedies further consumer protection by motivating manufacturers ... to give adequate warnings." *Id.* at 1199-1200.

This Court observed that Congress and the FDA have viewed state tort law as complementing, not obstructing, the goals of the FDCA. "In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." *Id.* at 1202.

Congress understands that state tort law is an indispensable partner to federal safety regulation. "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984)).

Indeed, in the 1962 amendments to the FDCA, Congress expressly limited the preemptive effect of the statute by stating:

> Nothing in the amendments made by this Act to the Federal Food, Drug and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.

Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962). The plain language of this provision makes clear that the FDCA does not preempt state law in the absence of a "direct and positive" conflict. As this Court observed in *Levine*, "[a]s it enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,' Congress took care to preserve state law." 129 S. Ct. at 1195-96 (internal citations omitted).

The Hatch-Waxman Amendments are part of this 70-year history and similarly do not categorically preempt failure-to-warn suits against generic manufacturers. There is no express preemption provision in the Amendments; rather, it is subject to the same saving provision enacted in 1962. If Congress had wished to depart from the usual rule governing other pharmaceuticals, it could have crafted a special preemption provision for generic drugs in its 1984 amendments. Congress is well aware of how to enact such special provisions. It did

so for medical devices in 1976,[11] for vaccines in 1986,[12] and for over-the-counter medications in 1997.[13]

In holding in *Bruesewitz v. Wyeth LLC*, No. 09-152 (Feb. 22, 2011), that the Vaccine Act of 1986 bars state-law design-defect claims against vaccine manufacturers, this Court reiterated that "we have previously expressed doubt that Congress would quietly preempt product-liability claims without providing a federal substitute." No. 09-152, slip op. at 16 (citing *Lohr*). In *Bruesewitz*, this Court observed that, in enacting the 1986 Vaccine Act, Congress deliberately departed from the regime applicable to pharmaceuticals and established a "no-fault compensation program 'designed to work faster and with greater ease than the civil tort system.'" *Id.* at 3 (citation omitted). In contrast, there is no similar no-fault compensation scheme available with respect to generic drugs, and no indication that Congress sought to displace traditional state-law tort remedies.

Establishing a categorical preemption of all state law claims against generic drug manufacturers would

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[11] *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (considering the effect of the express preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(a)).

[12] *Bruesewitz v. Wyeth LLC*, No. 09-152 (Feb. 22, 2011) (construing 42 U.S.C. §300aa-22(b)(1), enacted as part of the National Childhood Vaccine Injury Act of 1986).

[13] In 1997, Congress preempted certain state requirements concerning over-the-counter medications but expressly preserved product liability actions. *See* 21 U.S.C. §§ 379r(e), 379s(d).

create a dangerous asymmetry because it would make the availability of a compensatory tort remedy depend upon the fortuity of whether a patient receives a prescription for a name brand or generic drug. In enacting the Hatch-Waxman Amendments, Congress did not intend to create a categorical exemption from failure-to-warn liability for generic manufacturers.

CONCLUSION

The judgments below should be affirmed

Respectfully submitted,

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NOS. 09 - 993, 09 - 1039, & 09 - 1501

IN THE

Supreme Court of the United States

PLIVA, INC., ET AL., *Petitioners*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS ELIZABETH LLC, *Petitioner*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS, INC., *Petitioner*,

v.

JULIE DEMAHY, *Respondent*.

On Writs of Certiorari to the United States Courts of Appeals for the Eighth Circuit and for the Fifth Circuit

RESPONDENTS' PETITION FOR REHEARING

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RESPONDENTS' PETITION FOR REHEARING

Respondents Gladys Mensing and Julie Demahy hereby respectfully petition the Court to rehear *Pliva, Inc., v. Mensing*, No. 09-993; *Actavis Elizabeth, LLC v. Mensing*, No. 09-1039; and *Actavis, Inc. v. Demahy*, No. 09-1501. Respondents seek rehearing because the judgment of the Court rendered on June 23, 2011 does not follow from the rule announced by the Court in this case. The Court overlooks the fact that the Petitioner generic drug companies could have "independently" complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known were inadequate.

DISCUSSION

In the Opinion of the Court, this Court announced a new test for implied conflict preemption based on impossibility: "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Pliva, Inc. v. Mensing*, No. 09-993; *Actavis Elizabeth, LLC v. Mensing*, No. 09-1039; *Actavis, Inc. v. Demahy*, No. 09-1501, 2011 WL 2472790 (U.S. June 23, 2011), at *10 (citation omitted). The Court reasoned that "State tort law . . . required the Manufacturers to use a different, stronger label than the label they actually used," but that "Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels." *Id.* at *8. Therefore, because the Manufacturers could not independently change their labels, the Court found Respondents' failure-to-warn claims preempted.

But the Court's logic is erroneous, because it begins with a false premise. Contrary to the Court's reasoning, neither Minnesota nor Louisiana law required the Manufacturers to change their labels. Instead, what state tort law required was that the manufacturers not sell a drug that lacked adequate warnings. Resp'ts' Br. 29. The Petitioners could have satisfied this state law duty in either of two ways. As the Court recognized, Petitioners could have satisfied that duty by strengthening their warning labels; but that course of action required FDA approval and therefore could not have been accomplished independently. Alternatively, however, Petitioners could have satisfied their duty under state tort law by suspending sales of the product with a label that they knew or should have known was inadequate. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product"). That course of action was always available to them and could have been accomplished independently, without any action by the FDA.[1] Thus, it was not impossible for the Petitioners to comply with both federal and state law: they "could independently do under federal law what state law requires of" them.

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[1] Suspension of sales by the manufacturers of generic metoclopramide would not have risked injury to users of their products who needed access to the drug, because the name-brand product, Reglan, remains on the market. And the manufacturer of Reglan could have added an adequate warning to its label through the CBE process. *See Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009); 21 C.F.R. § 314.70(c).

A decision by Petitioners to stop selling generic metoclopramide with inadequate safety warnings would not only have satisfied their duties under Minnesota and Louisiana tort law; it would also have complied with their duties under the Federal Food, Drug, and Cosmetic Act (FDCA). As Justice Thomas noted in his concurrence in *Wyeth v. Levine*, "the statutory provisions governing FDA drug labeling, and the regulations promulgated thereunder, do not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA." 129 S. Ct. at 1210 (Thomas, J., concurring). Federal law prohibits the sale of misbranded drugs, 21 U.S.C. § 331, and deems a drug to be misbranded if it lacks "adequate warnings." 21 U.S.C. § 352(f)(2). Thus, Respondents' state law failure-to-warn claims "parallel" the duties imposed on drug manufacturers under federal law. This Court has repeatedly held that such parallel claims escape preemption, even under statutory schemes with express preemption provisions. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447-48 (2005); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Indeed, so far as Respondents are aware, the decision in this case represents the first and only time this Court has ever held a traditional state-law cause of action preempted where the duties imposed by that cause of action were parallel to requirements imposed by federal law.

The ruling of this Court rested on a false premise regarding the duties imposed by state law; the actual state law duties paralleled federal law and could have been satisfied by Petitioners independently, without any action by the FDA or any

other party. This Court should therefore rehear these cases in order to address this error in its reasoning.

CONCLUSION

For the foregoing reasons, Respondents Gladys Mensing and Julie Demahy urge this Court to grant this petition for rehearing.

July 18, 2011

Respectfully submitted,

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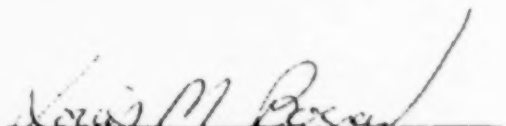
RESPONDENTS' RULE 44.1 CERTIFICATION OF COUNSEL

As counsel of record for Respondents Gladys Mensing and Julie Demahy, I hereby certify that this petition for rehearing is presented to the Court in good faith and not for purposes of delay.

July 18, 2011 Respectfully submitted,



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